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# **REMARKS**

### **Information Disclosure Statement:**

Applicants' submit the non-patent literature cited in the Information Disclosure Statement filed July 19, 2004 is already of record. These documents were cited in the international search report of the international phase for this application. Therefore, legible copies of these references need not be provided for the Information Disclosure Statement to satisfy the requirements of 37 C.F.R. §1.98(a)(2). Applicants have provided copies of the references so that the Examiner does not have to order these references from WIPO. A new PTO-1449 Form has been submitted with these references to replace the form the Examiner has both initialed and marked through.

# Rejections Under 35 U.S.C. §112:

Applicants maintain that the original claims satisfy the requirements of the 35 U.S.C. §112, second paragraph in that the percentages of the ingredients cited in the claims are clearly based on weight when reviewing the application as a whole, particularly the formulations described in the tables on pages 8-14. In addition, one skilled in the art would recognize the obvious error in using the abbreviation "W" instead of "UV" based on its use in the context of the claim and when considering the specification as a whole as evidenced by the Examiner's comments on page 2 of the Office Action. The above amendments have been made to eliminate these issues and expedite the prosecution of the application. The amendments are not necessary to render the claims patentable when interpreted in light of the specification.

## **Double Patenting:**

Applicants maintain claims 1 and 23-27 herein do not claim the same subject matter as claims 18 and 21-23 of U.S. Patent 6,649,150. Claim 18 of the '150 patent and the claims which depend thereon define a "powder" consisting essentially of 40% by weight of Emblicanin A,

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Emblicanin B, Pedunculagin and Punigluconin and less than about 1% by weight of flavonoids.

In contrast, claims 1 and 23-27 herein define an "extract" of Emblicanin officialis with these components. These claims encompass formulations which contain these components in a physical form other than a "powder."

On page 5, lines 26-34 of the specification it is stated that, "In general, the standardized extract is sold as a powder in packaged form..." This disclosure teaches that the extract is not limited to this 'powder in packaged form."

Page 6, lines 1-3, of the specification teach that the "standardized extract powdery material," can be "incorporated in a cosmetically or pharmaceutically acceptable carrier." The extract in this form is not a powder but a suspended solid. On page 4, lines 10-13, of the specification, reference is made to the publication entitled, "Ingredients/Emblica, Bearing Fruit (SIC), by Ratan K. Chaudhuri. The contents of this publication are incorporated into the specification by reference. (See page 19, lines 28-29 of the specification). On page 30 of this publication under the heading "Formulation guide" the use of "emblica cascading antioxidant," an extract from premium quality fruits, is said to be used as a "suspension." Claims 18 and 21-23 of U.S. Patent 6,649,150 define only powders, not suspensions. Therefore, claims 1 and 23-27 herein are not coextensive with any of the claims in U.S. Patent 6,649,150 and the double-patenting rejection under 35 U.S.C. §101 should be withdrawn.

#### Claims 23-26

The extract in each of claims 23-26 have a maximum absorbance (optical density) prescribed for only one wave-length whereas the powders of claims 21-23 of U.S. Patent 6,649,150 have the maximum absorbance prescribed for 5 wavelengths. Therefore, claims 23-26 herein are clearly not coextensive of any claims in U.S. Patent 6,649,150 and there is no basis for the double-patenting rejection of these claims under 35 U.S.C. §101.

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### **Obviousness type Double Patenting:**

Co-pending application no. 10/571,588

The provisional obviousness type double patenting rejection based on claims 16, 18 and 19 of co-pending application no. 10/571,588 is without basis in that the compositions therein are defined by completely different parameters than the compositions of claims 1-3, 10 and 11 herein; and are unobvious. The powders of claim 16 of the '588 application comprise at least 70 wt% low molecular weight tannins and are not prescribed by the 4 components found in the extracts and compositions of claims 1-3, 10 and 11herein. There is no direction or other basis for one skilled in the art to find the subject of the claims within either application to be obvious in view of the subject matter defined in the claims of the other.

The powders of claim 18 of the '588 application (and the compositions which they form/claim 19) are also patentably distinct from the powders of claims 1-3, 10 and 11 herein in that they are substantially to completely devoid of black specs, which is not an obvious feature. In addition, there is no mention of the 4 components required of the extracts claimed herein in claims 18 and 19 of the 588 application.

Furthermore, as the earlier filed application, should this "provisional" non-statutory obviousness-type double patenting rejection be the <u>only</u> remaining rejection, MPEP 804 (I)(B) provides this rejection should be withdrawn without filing a terminal disclaimer to allow this application to issue.

In view of the remarks above, applicants submit the provisional obviousness type double patenting rejection based on co-pending application no. 10/571588 should be withdrawn.

### US Patent 6,969,509

The provisional obviousness type double patenting rejection of composition claim 11 herein based on the method claims US Patent 6,969,509 is clearly without basis. The methods of the '509 patent were found to be patentably distinct from the powder compositions claimed in

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US Patent 6,649,150 and were required to be restricted from the application which issued as US Patent no. 6,649,150 patent. The compositions of claim 11, which contain "extracts," are clearly further distinguished from the method claims of the '509 patent.

The subject matter of claim 14 is also patentably distinct from that of claim 1 of U.S. Patent No. 6,969,509 in that the method is not restricted to the use of a powder. There is no hint or suggestion the extract can be used in other forms based on claim 1 of the U.S. Patent No. 6,969,509.

Furthermore, the composition of claim 11 and method of claim 14 prescribe the use of a "composition" having 90-99.7% by weight of the extract. The method of claim 1 of U.S. Patent 6,969,509 provides no hint or suggestion to select the use of such a concentrated composition. As such, the subject matter of these claims is patentably distinct from that of claim 1 of the '509 patent.

#### US Patent 6,649,150

Applicants also traverse the rejection for obviousness type double patenting of claims 1-7, 10-13 and 15-27 based on claims 1-17, 19 and 20 of U.S. Patent 6,649150. As discussed above, the subject matter of the claims in U.S. Patent No. 6,649,150 is directed to powders whereas the claims herein are not restricted to such a physical state. There is no evidence one skilled in the art would find it obvious to expand the physical forms for the components defined in the claims within U.S. Patent No. 6,649,150. Therefore the rejection based on obviousness type double-patenting should be withdrawn.

#### **Assignment Records:**

The assignment records at the U.S. Patent and Trademark Office indicate (incorrectly) that this application and U.S. Patent 6,649,150 do not have common assignees. The assignment

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records presently show Merck as a sole assignee of the present application and that U.S. Patent 6,649,150 is assigned to both Merck and Natreon Inc. Applicants will correct the assignment records of the USPTO to reflect the true assignees.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

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